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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,223	03/27/2006	Yoshinori Fukui	024918-0123	9403

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EXAMINER	
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ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,223	FUKUI ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *13-35,37-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/17/2005,3/27/2006,6/30/2006,2/4/2008.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-12 and 36) in the reply filed on 5/13/2008 is acknowledged. Claims 13-35 and 37-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-12 and 36 are under examination.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 5/17/2005, 3/27/2006, 6/30/2006, and 2/4/2008 have been considered by the examiner. Signed copies are attached hereto. It is noted that the IDS of 3/27/2006 appears to be a duplicate of the IDS submitted 5/17/2005 and lists only duplicative references. As a result, the IDS filed 5/17/2005 has been lined through. The two sequence alignments that have been submitted with the 2/4/2008 IDS have not been considered because they do not contain a date.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the priority document JP-2002-342683 (filed 11/26/2002) (published as JP 2004-177226A) is included in the present case. However, the priority document is in Japanese. The examiner was able to locate an English language machine translation from the Patent Abstracts of Japan (PAJ) database. A copy of the English language translation of the claims and description is attached hereto.

Claim Objections

4. Claim 6 is objected to because of the following informalities: there appears to be a typo in line 3 related to the word "acted." It appears that the antibody against ELMO or its C terminus domain should be "attached" to DOCK2 or its SH3 domain. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 6, and 7 recite that the method is drawn to screening a substance interfering in the association of DOCK2 and ELMO. However, the measuring or estimating step of each of the claims is drawn to determining the level of formation of association. The claim language is unclear and confusing because the language of the measuring/estimating step does not demonstrate the interference stated in the preamble. In order to overcome this rejection the examiner suggests using the phrase "level of interference" instead of the phrase "level of formation" in claims 1-4, 6, and 7. Claims 5 and 8-10 are rejected as depending from rejected claims.

7. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Lines 3 and 4 state that "an antibody against ELMO or its C terminus domain is acted [attached] to DOCK2 or its SH3 domain fractionated by an antibody..." It is unclear what is meant by the term "fractionated" in the context of the claim.

8. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 11 is also indefinite because the preamble, as written, is unclear and confusing. The preamble recites "a method for searching a therapeutic agent for immune related diseases..." It is unclear how the therapeutic agents and immune related diseases are to be related. Therapeutic agents do not have immune related diseases. Are the therapeutic agents supposed to function to "treat" immune related diseases or have some other functional relationship to the immune related diseases? If so, the claim should be clarified to clearly state the correlation.

Claim 11 is also indefinite because the functional step does not reasonably correlate with the preamble of the claim. The claim recites "a method for searching a therapeutic agent for immune related diseases…wherein the method for screening a substance interfering in the association of DOCK2 and ELMO according to claim 1 is used." The claim appears to be a process-by-process claim. However, it is unclear how the screening method correlates with the preamble, which is a method for searching a therapeutic agent for immune related diseases.

9. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble, as written, is unclear and confusing. The preamble recites "a method for searching a therapeutic agent for diseases caused by the suppression of lymphocyte migration..." It is unclear how the therapeutic agents and diseases caused by the suppression of lymphocyte migration are related. Therapeutic agents do not have diseases caused by the suppression of lymphocyte migration. Are the therapeutic agents supposed to function to "treat" diseases caused by the suppression of lymphocyte migration or have some other functional relationship to the diseases caused by the suppression of lymphocyte migration? If so, the claim should be clarified to clearly state the correlation.

Claim 12 is also indefinite because the functional step does not reasonably correlate with the preamble of the claim. The claim recites "a method for searching a therapeutic agent for diseases caused by the suppression of lymphocyte migration…wherein the method for screening a substance interfering in the association of DOCK2 and ELMO according to claim 1 is used." The claim appears to be a process-by-process claim. However, it is unclear how the screening method correlates with the preamble, which is a method for searching a therapeutic agent for diseases caused by the suppression of lymphocyte migration.

10. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "such as" in line 1 renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 112, First Paragraph

Scope of Enablement

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability, 5) existence of working samples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 1-4, and 6 recite an "estimating" step wherein the level of formation of association between DOCK2 and ELMO is "estimated." However, the claims do not specifically recite how this estimation step is to be carried out. As a result the claims encompass all means of estimating The specification, however, recites only limited means of estimating. The specification states that the formation of association is measured by detecting GTP-binding form of activated-Rac (page 8, lines 26-27) (compare instant claim 7). The difference in scope between that is claimed and what is taught in the specification regarding the estimating step, illuminates the fact that the claims are single means claims. A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt, 708 F.2d 712, 714-715, 218 USPQ 195, 197 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See MPEP 2164.08(a).

Dependent claim 5 shares the single means problem of independent claim 1 because although claim 5 recites the addition of a marker protein and/or peptide tag, there is no requirement in the claim to use the marker or peptide tag to measure anything. Similarly, claims 8-12 do not further limit the estimating step or provide any additional limitation for the breadth of the estimating step.

Claim Rejections - 35 USC § 112, First Paragraph

Enablement

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability, 5) existence of working samples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claim recites a therapeutic agent for immune related diseases such as allergy, autoimmune diseases, GvH and graft rejection, obtained by the searching method according to claim 11. Claim 36 is a product-by-process and reach-through claim.

Patentability of a product-by-process claims is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it (*In re Thorpe* 227 USPQ 964 (Fed. Cir. 1985)). In order to meet the enablement requirement, the specification must teach how to make and use the full scope of the claimed invention without undue experimentation. The claimed invention in a product-by-process claim is the product, which, in this case, is a genus of therapeutic agents.

There is no teaching in the specification or the claims as to the structure of a representative number of claimed therapeutic agents. There is no teaching in the specification of any chemical or physical characteristics of the representative claimed therapeutic agents or their function. Additionally, because no function is required, the breadth of the therapeutic agents of claim 36 encompass inoperative embodiments. Broad claims may be rejected merely because they read on a significant number of inoperative species when examiner sets forth reasonable grounds in support of his or her conclusions that the claims may read upon inoperative subject matter and it becomes incumbent upon applicant either to reasonably limit claims to approximate area where operativeness has not been challenged or to rebut examiner's challenge by submission of representative evidence or by persuasive arguments based on known laws of physics and chemistry (see *In re Cook and Merigold*, 169 USPQ 298 (CCPA 1971)). Further, there are no working examples of any of the therapeutic agents in claim 36.

Claim 36 is also a reach-through claim that is analogous to the claims at issue in *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Reach-through claims refer to claims for products or uses for products when experimental data is provided for screening

methods or tools for the identification of such products. In *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) the CAFC upheld a lower court's decision noting that while a screening method was provided for the identification of COX-2 inhibitors, no COX-2 inhibitors had been identified and no treatment demonstrated.

Due to the large quantity of experimentation necessary to determine how to make or use the claimed genus of therapeutic agents, the lack of direction/guidance presented in the specification regarding same, the absence of sufficient working examples directed to same, the complex nature of the invention, and the breadth of the claims which fail to recite any specific therapeutic agent, its structure, function, or physical characteristics, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, First Paragraph

Written Description

15. Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The claim recites a therapeutic agent for immune related diseases such as allergy, autoimmune diseases, GvH and graft rejection, obtained by the searching method according to claim 11. Claim 36 is a product-by-process and reach-through claim.

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 19 USPQ2d 1111, (Fed. Cir. 1991), states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117). A review of the language of the claim indicates that these claims are drawn to a genus, i.e., therapeutic agents.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states, "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

There is no description of the structure of a representative number of claimed therapeutic compounds. There is no description of chemical or physical characteristics of the representative claimed compounds of their function. Claim 36 is analogous to the claims at issue in *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997)(description of how to obtain compounds not sufficient without description of what the compounds are). See also *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993); *In re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967).

In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus, which is a therapeutic agent. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features (see, *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1895 (Fed. Cir. 2004); accord *Ex Parte Kubin*, 2007-0819, BPAI 31 May 2007, opinion at p. 16, paragraph 1). The specification does not clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Hewitt et al., US Patent 4,996,193 (26 February 1991).

Instant claim 36 is drawn to a therapeutic agent. The '193 patent teaches cyclosporine as a therapeutic agent for treating autoimmune diseases (abstract).

Applicant is reminded that claim 36 is a product-by-process claim and that the patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it (*In re Thorpe* 227 USPQ 964 (Fed. Cir. 1985)).

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Examiner, Art Unit 1647